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NOTICE OF ALLOWANCE AND FEE(S) DUE

20583

7590

05/15/2009

JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652 DATE MAILED: 05/15/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,406	03/14/2005	Rafal Swiercz	9471-011-999	8301

TITLE OF INVENTION: MODIFIED PLASMINOGEN ACTIVATOR INHIBITOR TYPE-1 AND METHODS BASED THEREON

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/17/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

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maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 20583 7590 05/15/2009 Certificate of Mailing or Transmission JONES DAY I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. **222 EAST 41ST ST** NEW YORK, NY 10017 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/506.406 03/14/2005 Rafal Swiercz 9471-011-999 8301 TITLE OF INVENTION: MODIFIED PLASMINOGEN ACTIVATOR INHIBITOR TYPE-1 AND METHODS BASED THEREON APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$0 \$1810 08/17/2009 **EXAMINER** ART UNIT CLASS-SUBCLASS ROBINSON, HOPE A 1652 530-350000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			ROBINSON, HOPE A	
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			1652	
			DATE MAILED: 05/15/200	9

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	10/506,406	SWIERCZ ET AL.	
Notice of Allowability	Examiner	Art Unit	
	HOPE A. ROBINSON	1652	
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	ears on the cover sheet with 5 (OR REMAINS) CLOSED in t) or other appropriate commun RIGHTS. This application is sul	the correspondence address his application. If not included ication will be mailed in due course. THIS	
1. \square This communication is responsive to $4/27/09$.			
2. \square The allowed claim(s) is/are $\underline{1,2,4-6,9-16,21-23,29-31}$ and	<u>33</u> .		
3. Acknowledgment is made of a claim for foreign priority u a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority do International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which giv 5. CORRECTED DRAWINGS (as "replacement sheets") mu (a) including changes required by the Notice of Draftspers 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner Paper No./Mail Date Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 2) each sheet. Replacement sheet(s) should be labeled as such in the such as the such as the application number (see 37 CFR 2) each sheet. Replacement sheet(s) should be labeled as such in the such as the application number (see 37 CFR 2) each sheet. Replacement sheet(s) should be labeled as such in the such as the application number (see 37 CFR 2) each sheet. Replacement sheet(s) should be labeled as such in the such as the application number (see 37 CFR 2) each sheet.	e been received. e been received in Application ocuments have been received in Application ocuments have been received in Application of this communication to file and MENT of this application. Initial Note the attached EXAMores reason(s) why the oath or do st be submitted. Initial State of the Attached EXAMores reason(s) why the oath or do st be submitted. In the Application of the Attached EXAMores reason(s) why the oath or do st be submitted. In the Application of the Applicat	No In this national stage application from the reply complying with the requirements INER'S AMENDMENT or NOTICE OF eclaration is deficient. PTO-948) attached In the Office action of drawings in the front (not the back) of	
DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT	osit of BIOLOGICAL MATER	RIAL must be submitted. Note the	
Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. ☐ Interview Sun Paper No./M 7.	rmal Patent Application nmary (PTO-413), ail Date mendment/Comment tatement of Reasons for Allowance	
/Hope A. Robinson/ Primary Examiner, Art Unit 1652			

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EXAMINER'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 19, 2009 has been entered.

- 2. The Supplemental Amendment filed on April 27, 2009 has been received and entered.
- 3. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
- 4. Authorization of this Examiner's amendment was given in a telephone interview with Ms. Susie Cheng on May 4, 2009.
- 5. The Claims have been amended as follows:

Please **cancel** claim 32 without prejudice.

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inhibits urokinase plasminogen activator.

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1. (Currently Amended) A modified plasminogen activator inhibitor type-1 (PAI-1) molecule comprising [the] an amino acid sequence that is at least 95% identical to the amino acid sequence of SEQ ID NO:2, in which one or more amino acid residues are each substituted by an amino acid residue that contains a sulfhydryl group, such that one or more disulfide bridges are formed at a position selected from the group consisting of 31, 97, 192, 197, 347, and 355 of SEQ ID NO:2, [and] wherein said modified PAI-1 molecule has a half-life that is longer than the half-life of a corresponding wild-type PAI-1 molecule, and wherein said modified PAI-1 molecule

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- 2. (Currently Amended) The modified PAI-1 molecule of claim 1, which has [an] a half-life of 3 hours, 6 hours, 10 hours, 20 hours, 50 hours, 60 hours, 70 hours, 90 hours, 100 hours, 150 hours, 200 hours, 10 days, 12 days, 16 days, 30 days, or 60 days.
- 4. (Currently Amended) The modified PAI-1 molecule of claim 1, wherein said residue that contains a sulfhydryl group is cysteine.
- 5. (Currently Amended) A modified plasminogen activator inhibitor type-1

 (PAI-1) molecule comprising the amino acid sequence of SEQ ID NO:2, [wherein]

 except for substitution by an amino acid residue that contains a sulfhydryl group at one
 or more [amino acid residues of SEQ ID NO:2 is substituted by an amino acid residue

that contains a sulfhydryl group at] of positions 31, 97, 192, 197, 347, or 355 of SEQ ID NO:2, wherein said modified PAI-1 molecule has a half-life that is longer than the half-life of a corresponding wild-type PAI-1 molecule, and wherein said modified PAI-1 molecule inhibits urokinase plasminogen activator.

- 6. (Currently Amended) A modified plasminogen activator inhibitor type-1 (PAI- 1) molecule comprising the amino acid sequence of SEQ ID NO:2, [wherein] except for substitution by an amino acid residue that contains a sulfhydryl group at [one or more amino acid residues is substituted by an amino acid residue that contains a sulfhydryl group at] positions (i) 31 and 97 of SEQ ID NO:2; (ii) 192 and 347 of SEQ ID NO:2; (iii) 197 and 355 of SEQ ID NO:2; (iv) 31, 97, 192, and 347 of SEQ ID NO:2; (v) 31, 97, 197, and 355 of SEQ ID NO:2; (vi) 192, 197, 347, and 355 of SEQ ID NO:2; or (vii) 31, 97, 192, 197, 347, and 355 of SEQ ID NO:2, [and] wherein said modified PAI-1 molecule has a half-life that is longer than the half-life of a corresponding wild-type PAI-1 molecule, and wherein said modified PAI-1 molecule inhibits urokinase plasminogen activator.
- 9.(Currently Amended) The modified PAI-1 molecule of claim 1, wherein said molecule inhibits tissue plasminogen activator.
- 10. (Currently Amended) The modified PAI-1 molecule of claim 1, wherein said molecule augments endogenous PAI-1 function.

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- 11. (Currently Amended) A method of producing a modified plasminogen activator inhibitor type-1 molecule said method comprising:
- (a) introducing into a cell a nucleic acid molecule encoding a modified PAI-1 molecule comprising [the] an amino acid sequence that is at least 95% identical to the amino acid sequence of SEQ ID NO:2, in which one or more amino acid residues are each substituted by an amino acid residue that contains a sulfhydryl group, such that one or more disulfide bridges are formed at a position selected from the group consisting of 31, 97, 192, 197, 347, and 355 of SEQ ID NO:2, [and] wherein said modified PAI-1 molecule has a half-life that is longer than the half-life of a corresponding wild-type PAI-1 molecule and wherein said modified PAI-1 molecule inhibits urokinase plasminogen activator; and
- (b) culturing the cell under conditions suitable for expression of the modified PAI-1 molecule.
- 12. (Currently Amended) A method of producing a modified plasminogen activator inhibitor type- 1 (PAI- 1) molecule, said method comprising:
- (a) introducing into a cell a nucleic acid molecule encoding a modified PAI-1 molecule said molecule comprising the amino acid sequence of SEQ ID NO:2, [wherein] except for substitution by an amino acid residue that contains a sulfhydryl group [one or more amino acid residues of SEQ ID NO:2 are each substituted by an amino acid residue that contains a sulthydryl group] at positions 31, 97, 192, 197, 347,

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[and] or 355 of SEQ ID NO:2, wherein said modified PAI-1 molecule has a half life that is longer than the half-life of a corresponding wild-type PAI-1 molecule, <u>and</u> wherein said modified PAI-1 molecule inhibits urokinase plasminogen activator; and

- (b) culturing the cell under conditions suitable for expression of the modified PAI-1 molecule.
- 13. (Currently Amended) A method of producing a modified plasminogen activator inhibitor type-1(PAI-1) molecule, said method comprising:
- (a) introducing into a cell a nucleic acid molecule encoding a modified PAI-1 molecule, said molecule comprising the amino acid sequence of SEQ ID NO:2, [in which] except for substitution by an amino acid residue that contains a sulfhydryl group [one or more amino acid residues are each substituted by an amino acid residue that contains a sulfhydryl group] at positions (i) 31 and 97; (ii) 192 and 347; (iii) 197 and 355; (iv) 31, 97, 192, and 347; (v) 31, 97, 197, and 355; (vi) 192, 197, 347, and 355; or (vii) 31, 97, 192, 197, 347, and 355, [and] wherein said modified PAI-1 molecule has a half life that is longer than the half-life of a corresponding wild-type PAI-1 molecule, and wherein said modified PAI-1 molecule inhibits urokinase plasminogen activator; and
- (b) culturing the cell under conditions suitable for expression of the modified PAI-1 molecule.

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15. (Currently Amended) A method of treating cancer in a subject in need thereof [suffering therefrom], said method comprising administering to [a] the subject [in which such treatment is desired] an effective amount of the modified PAI-1 molecule of claim 1.

16.(Currently Amended) The method of claim 15, wherein said cancer is selected from the group consisting of breast cancer, colon cancer, ovarian cancer, lung cancer, prostate cancer, melanoma, leukemia, lung cancer, skin cancer, pancreatic cancer, bladder cancer, sarcoma, and uterine cancer.

- 21. (Currently Amended) A method of treating urokinase plasminogen activator-mediated fibrinolysis in a subject <u>in need thereof</u>, said method comprising administering to [a] <u>the</u> subject [in which such treatment is desired] an effective amount of the modified PAI-1 molecule of claim 1.
- 22. (Currently Amended) A method of treating tissue plasminogen activator-mediated fibrinolysis in a subject in need thereof, said method comprising administering to [a] the subject [in which such treatment is desired] an effective amount of the modified PAI-1 molecule of claim 1.
- 23. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of the modified PAI- 1 molecule of claim 1[;] and a pharmaceutically acceptable carrier.

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29. (Currently Amended) A modified plasminogen

activator inhibitor type-1(PAI-1) molecule comprising the amino acid sequence of SEQ ID NO:2 [wherein] except for substitution by an amino acid residue that contains a sulfhydryl group [amino acid residues] at positions: (i) 31 and 97 of SEQ ID NO:2; (ii) 192 and 347 of SEQ ID NO:2; (iii) 197 and 355 of SEQ ID NO:2; (iv) 31, 97, 192, and 347 of SEQ ID NO:2; (v) 31, 97, 197, and 355 of SEQ ID NO:2; (vi) 192, 197, 347 and 355 of SEQ ID NO:2; or (vii) 31, 97, 192, 197, 347, and 355 of SEQ ID NO:2, [are substituted with amino acid residues that contain a sulfhydryl group], wherein said modified PAI-1 molecule inhibits urokinase plasminogen activator.

- 30. (Currently Amended) A method of producing a modified plasminogen activator inhibitor type-1 (PAI-1) molecule said method comprising:
- (a) introducing into a cell a nucleic acid molecule encoding the modified PAI-1 molecule of claim 1; and
- (b) culturing the cell under conditions suitable for expression of the modified PAI-1 molecule.
- 33. (Currently Amended) The [modified] modified PAI-1 molecule of any one of claims 1, 5, [and] or 6, wherein the half-life is an *in vivo* half-life.

EXAMINER'S COMMENTS

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4. The restriction requirement of record has been withdrawn in part, rejoining method claims.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

6. Claims 1-2, 4-6, 9-16, 21-23, 29-31 and 33 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652